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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of: M. Seul et al.	
Serial No. 09/448,420	Group Art Unit: 1639
Filed: 11/22/1999	Examiner: P. Ponnaluri
For: Color-Encoding and *in-situ* Interrogation of Matrix-Coupled Chemical Compounds	

Commissioner for Patents
PO Box 1450
Alexandria VA 22313-1450

VIA FAX: (703) 872-9306

Petition for Examiner to Comply with MPEP 1208(A)(10), subparts (c)&(e)

Dear Sir:

Applicants hereby petition for the final rejection to be withdrawn and prosecution to be re-opened in this matter, for the reasons set forth below. The Commissioner is authorized to charge Deposit Account No. 502088 for the $130 due for this petition, or any other costs connected with this matter.

The Examiner mailed an Answer to Applicants' Appeal Brief in this matter on April 21, 2004. The Answer is clearly not in compliance with MPEP Section 1208(A)(10), subparts (c)&(e), which respectively require:

> (c) For each rejection under **35 U.S.C. 102**, the examiner's answer, or single prior action, shall explain why the rejected claims are anticipated or not patentable under **35 U.S.C. 102**, pointing out where ***all of the specific limitations recited in the rejected claims are found in the prior art relied upon in the rejection.*** [emphasis added]

> (e) For each rejection under **35 U.S.C. 102** or 103 where there are questions as to how limitations in the claims correspond to features in the prior art even after the examiner complies with the requirements of paragraphs (c) and (d) of this section, ***the examiner shall compare at least one of the rejected claims feature by feature with the prior art relied on in the rejection. The comparison shall align the language of the claim side-by-side with a reference to the specific page, line number, drawing reference number, and quotation from the prior art, as appropriate.*** [emphasis added]

Applicants have pointed out clearly in their Appeal Brief that each of the three references relied upon to support the three separate rejections under 35 U.S.C. 102 (one of which is also the primary reference for the sole Section 103 rejection) do not meet the limitations set forth in the claims. The only statements in the Answer which attempt any sort of correlation between the claim elements and the prior art are the following:

Page 4, last paragraph of the Answer:

> The instant claims briefly recite a method of identifying a compound of interest in a library of compounds, each of said compounds being bound to a solid support, and prepared by split synthesis, adding one or more tags to the solid support, and decoding the code composed of one or more tags; performing an assay capable of indicating that any compound in the library has a property of interest; decoding the code composed of one or more tags to identify the compound, wherein the decoding step is carried out without isolating the solid support comprising the compound from other solid support and without detaching the tag from the solid support, and wherein the decoding step comprises *in situ* optical interrogation of the tag.

Page 5, first paragraph:

Boyce et al disclose peptide steroidal receptors for opoid peptides. The reference discloses split synthesis using polystyrene beads. The reference discloses that the combinatorial synthesis led to 10^2 variants of V1 and was encoded with eight molecular tags using a binary tagging method. Finally encoded split synthesis was employed with eight more tags to complete V2. This double split synthesis led to a 10^4 member library in which each different member of the library was attached to a different synthesis bead (refers to steps a)-e) of the instant claims). The reference discloses to test the library for receptor substrate binding. The binding screen was conducted as a solid phase assay in which a sample of the beads were treated with a dilute solution of substrate tethered to an intensely colored dye. The dye-linked receptor library was then screened for binding with encephalon (refers to the instant claim step f)). The reference discloses that many beads had developed light orange coloration and few turned bright red (refers to said decoding step comprises in-situ optical interrogation of the instant claims). The reference discloses that bright red beads (refers to other solid supports) and decoded their synthetic history . Thus, the reference clearly anticipates the claimed invention.

Page 11, second paragraph:

Appellants arguments have been fully considered and are not persuasive, since Boyce et al teach that the dye-linked receptor library was then screened for binding with encephalon (refers to the instant claim step f)); and Boyce et al teach 'binding was detected by simple inspection, the library beads bound to the substrate picked up the colored dyes (or turned red) (refers to the instant claim step g)). Thus, Boyce et al teaches both steps f) and g) of the instant claims.

Page 14, second paragraph:

Appellants assertions and arguments regarding the instant claim 129 steps f) and g) and difference of these steps compared to Dower et al have been considered and are not persuasive. Appellant's interpretation of Dower et al teaching of only step (f) of the instant claims and not step (g) is improper. Dower et al clearly teach 'after the receptor assay (the receptor assay refers to the instant claim step (f)), the positive beads (identify the compound of interest) are identified and isolated using fluorescent activated solid support sorting (which refers to the instant claim decoding the tag to identify the compound, wherein decoding comprises optical interrogation). Thus, Dower et al teach steps (f) and (g) of the instant claims.

Page 15, last paragraph, to page 16, first paragraph:

Appellant's assertions have been considered and are not persuasive because, the instant claim step (g) recites 'decoding to identify the compound associated with the code' which refers to identification of positive bead with the compound attached to the bead. In the instant claim step © recites the property of the code (i.e., capable of determining reaction sequence by optical interrogation) used in the claimed method, however the method steps, especially step g) does not recite that the reaction sequence or the structure or sequence of the compound attached to the bead is identified by in-situ optical interrogation . Dower et al further teach that the 'identifier tag' provides a means whereby one can identify which monomer reactions an individual solid support has experienced in the synthesis of oligomer and the identifier tag records the steps in synthesis series. Dower et al teach that the identifier tag is any recognizable feature, including microscopically distinguishable shape or size, color, optical density etc, or differently absorbing or emitting light (refers to the instant claim 'code' which is identified by the optical interrogation) (i.e., see page 10, under types of identifier tags), thus Dower et al clearly teach the use of identifier tags to determine the structure or sequence of the compound or the sequence of the reaction series the solid support has undergone. Thus, the reference clearly anticipates the claimed invention.

and, page 21, last paragraph:

Appellants argue that Dower do not mention anywhere that with respect to any type of identifier tags discussed the 'decoding step is carried out without isolating the solid support of interest from other solid supports.' Appellants arguments are not persuasive, because Dower et al clearly teach 'after the receptor assay (the receptor assay refers to the instant claim step (f)), the positive beads (identify the compound of interest) are identified and isolated using fluorescent activated solid support sorting , which refers to the instant claim decoding the tag to identify the compound, wherein decoding comprises optical interrogation. Thus the combined teachings of Dower et al and Metzeker clearly read the claimed invention.

Even without considering the additional limitations in the dependent claims at issue (Nos. 130-152 and 154-166) it is clear that the elements in claim 129 (the only independent claim at issue) have not been compared to the prior art in accordance with the requirements of MPEP 1208(A)(10), subparts (c)&(e). Claim 129 is set forth below:

129. A method of identifying a compound of interest in a library of compounds, each of said compounds being bound to a solid support and being produced by a unique reaction series composed of N reaction steps, wherein N is an integer of at least 2, and wherein each compound is produced from components which are independently the same or different, the method comprising:

(a) dividing a population of solid support into M batches, wherein M is an integer greater than 1;

(b) reacting each of the M batches of solid support with a component, so that the component forms a bond with the solid support;

(c) adding to one or more batches, prior to (b), concurrently with (b), or subsequently to (b), one or more tag(s), each tag able to be attached to the solid support and able to be identified by optical interrogation, wherein said one or more tag(s) constitutes a code, which code is uniquely associated with a compound and a corresponding reaction sequence and is determined by optical interrogation;

(d) recombining all of said M batches after (b) and (c);

(e) repeating (a) to (d) for N-1 times, or repeating (a) to (d) for N-2 times followed by repeating (a) to (c) once, to produce a library of compounds;

(f) performing an assay capable of indicating that any compound in the library has a property of interest; and

(g) decoding the code composed of one or more tag(s) to identify the compound associated with the code, wherein the decoding step is carried out without isolating the solid support comprising the compound having the property of interest from the other solid supports and without detaching any of the tag(s) from the solid support comprising the compound having the property of interest and wherein said decoding step comprises in-situ optical interrogation of the tag(s).

Applicants are petitioning for a remedy for the Examiner's failure to comply with MPEP 1208(A)(10), subparts (c)&(e) not merely because its requirements were not met, but because the Examiner has intentionally failed to comply in an attempt to hide the fact that none of the rejections are supported by the references cited. Applicants argued in their Brief (and previously) that several steps in claim 129 are not in the prior art. The Examiner is well aware that, as in the claim 129 parts (f) and (g), the process of combinatorial synthesis described in all of the prior art references is a two-step process: (i) performing an assay capable of indicating that any compound in the library of compounds has a property of interest; and (ii) decoding the code [the code is composed of one or more tag(s) in claim 129 but not in the prior art processes] to identify the compound associated with the code. The Examiner is also aware that the "decoding the code" in step (g) refers back to step (c) of claim 129, which states:

(c)adding to one or more batches, prior to (b), concurrently with (b), or subsequently to (b), one or more tag(s), each tag able to be attached to the solid support and able to be identified by optical interrogation, wherein said one or more tag(s) *constitutes a code, which code is uniquely associated with a compound and a corresponding reaction sequence and is determined by optical interrogation* [emphasis added]

The Examiner is also well aware that the following required sub-steps of step (g):

> the decoding step is carried out without isolating the solid support comprising the compound having the property of interest from the other solid supports and without detaching any of the tag(s) from the solid support comprising the compound having the property of interest and wherein said decoding step comprises in-situ optical interrogation of the tag(s)

are not referring to "performing an assay" in step (f), but rather refer to decoding the "compound/reaction encoding" of step (c). Nevertheless, in a transparent attempt to support the rejections, the Examiner asserts that "decoding" in step (g) is referring to discrimination of positive and negative events by the assay in step (f), even though all the language in the claim itself makes clear that "decoding" refers to the "code" in step (c), and does not refer to assay step (f). The Examiner then concludes that because the prior art processes describe "optical interrogation" for discriminating positive and negative *assay events*, the "decoding" of step (g) is disclosed. But the Examiner ignores the plain language and meaning of the claim in making this conclusion, and moreover, the Examiner ignores the fact that all the references describe separate steps, just like in the claim; *i.e.*, the references all disclose an assay step for discrimination of positive and negative events (where optical interrogation is sometimes used) and also disclose *separate* "compound/reaction encoding and decoding" steps (where the kind of optical interrogation described in step (g) is not used).

But the Examiner has never explained where in the references the following required steps in claim 129 appear:

> (a) dividing a population of solid support into M batches, wherein M is an integer greater than 1;

(b) reacting each of the M batches of solid support with a component, so that the component forms a bond with the solid support;

(c) adding to one or more batches, prior to (b), concurrently with (b), or subsequently to (b), one or more tag(s), each tag able to be attached to the solid support and able to be identified by optical interrogation, wherein said one or more tag(s) constitutes a code, which code is uniquely associated with a compound and a corresponding reaction sequence and is determined by optical interrogation;

(d) recombining all of said M batches after (b) and (c);

(e) repeating (a) to (d) for N-1 times, or repeating (a) to (d) for N-2 times followed by repeating (a) to (c) once, to produce a library of compounds;

(f) performing an assay capable of indicating that any compound in the library has a property of interest...

Most ostensibly, if the Examiner is correct in the assertion that "decoding the code" in step (g) can properly refer to a "code" which is used to identify positive beads in the assay of step (f), then, following the establishment of such "code" (pursuant to step (c) of claim 129) the references must disclose the steps in claim 129 (d) and (e) as well, in order to anticipate. But none of the references disclose that following the assay step, the batches are recombined (step (d)), and then, that the "divide" "react" "encode" and "recombine" steps required in step (e) are performed. Upon realizing that these elements were missing the analysis, the Examiner chose to not match up the claim elements against the prior art references, as required.

In view of the Examiner's knowing failure to comply with MPEP 1208(A)(10), subparts (c)&(e), Applicants request that the Examiner be required to withdraw the final rejection and reopen prosecution, in accordance with the procedures *permitting* the Examiner to do so, in Rule 1208.03. Applicants feel

this is the only appropriate relief because it is clear that the Examiner will not voluntarily reopen prosecution under Rule 1208.03, notwithstanding the unsupportable position set forth in the Answer. Applicants have made numerous requests to the Examiner and her supervisor to do so, none of which have been granted.

The Board of Appeals & Interferences should not be forced to waste its time on this matter, where the Examiner has no position and additionally has deliberately ignored the rules and procedures required. Also, the public should not suffer the detrimental effect of a multi-year extension of the patent which will result from this application (pursuant to an extension of the patent term under 35 USC 154(b), due to the time lost from this appeal) because of the Examiner's knowingly improper actions.

Respectfully Submitted,

Dated:4/26/2004

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The Commissioner is hereby authorized to charge any fees due in connection with this submission and not otherwise covered by payment included herewith, or to credit any overpayment, to Deposit Account No. 502088.

I hereby certify that, on the date indicated below, this correspondence was sent by fax to the Commissioner for Patents, at (703) 872-9306.

By: _____ Date: